DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

November 26, 2014

Covidien LLC
Richelle Hover
Regulatory Affairs Specialist
15 Hampshire St
Mansfield, MA 02048

Re: K142695
Trade/Device Name: Cytosponge™ Cell Collection Device
Regulation Number: 21 CFR 874.4710
Regulation Name: Esophagoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOX
Dated: September 19, 2014
Received: September 22, 2014

Dear Richelle Hover,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K142695

Device Name
Cytosponge™ Cell Collection Device

Indications for Use *(Describe)*
The Cytosponge™ Cell Collection Device is indicated for use in the collection and retrieval of surface cells in the esophagus.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) Summary

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Covidien llc
15 Hampshire Street
Mansfield, MA 02048

Contact: Richelle Hover
540 Oakmead Pkwy
Sunnyvale, CA 94085
Phone: (408) 328-7342
Facsimile: (408) 328-7342 (same as phone#)
Date Prepared: November 19, 2014

Name of Subject Device

Cytosponge™ Cell Collection Device

Establishment Registration Number/Owner Operator Number

Establishment Registration Number: 3004904811
Owner/Operator Number: 1282497

Legal Manufacturer:
Covidien, llc
15 Hampshire Street
Mansfield, MA 02048

Manufacturing Facility:
Covidien, Formerly BÂRRX Medical, Inc.
540 Oakmead Parkway
Sunnyvale, CA 94085

Common or Usual Name

Esophagoscope (flexible or rigid)

Regulation Description

Description: Esophagoscope (flexible or rigid) and accessories
Classification: Class II, 21 CFR 874.4710
Product Code: EOX
Classification Panel: Ear Nose & Throat Panel

Predicate Devices

Primary Predicate:

- Cell-Mate Mass Cytology Cellular Retrieval System (K934193)

Reference Predicate:

- US Endoscopy Cytology Brush (K103437)

Device Description

The subject device the Cytosponge™ Cell Collection Device is a sterile single-use device. The Cytosponge™ Cell Collection Device consists of a clear, size 00 vegetable-material-derived capsule, which holds a 30mm spherical sponge inside of the capsule. The capsule containing the sponge is attached to silicone-coated braided polyester suture. The suture is attached and secured to a retainer card via an ABS plug. The Cytosponge™ Cell Collection Device consists of a swallowable capsule, which dissolves in the stomach, releasing a self-expandable sponge. The sponge is then retrieved from the esophagus using an attached cord; during the retrieval process, the sponge collects cells from the outer layer of esophageal tissue

Indication for Use

The Cytosponge™ Cell Collection Device is indicated for use in the collection and retrieval of surface cells in the esophagus.

Technological Characteristics of Device Compared to Predicate Devices

The Cytosponge™ Cell Collection Device is substantially equivalent to the legally marketed Cell-Mate Mass Cytology Cellular Retrieval System in terms of intended use, principle of operation, technological characteristics, ergonomics of patient –user interface, anatomical location, operating instructions and single-use disposition.

The Cytosponge™ Cell Collection Device is also substantially equivalent to the legally marketed US Endoscopy Cytology Brush Endoscopy brush in terms of indications for use, anatomical location of use and single-use disposition.

Summary of Testing Performed

Verification and Validation activity for the Cytosponge™ Cell Collection Device consisted of animal testing to support the indication for use, biocompatibility testing, sterilization validation, packaging validation, shelf life testing, user validation, and bench performance testing which consisted of the following tests: (1) suture length testing (2) dissolution testing (3) sponge diameter testing (4) suture tensile testing (5) and laceration testing.

Conclusion

Covidien, llc considers the Cytosponge™ Cell Collection Device to be substantially equivalent to legally marketed predicates: Cell-Mate Mass Cytology Cellular Retrieval System (K934193) and US Endoscopy Cytology Brush (K103437).

The test results and compliance with applicable standards provide reasonable assurance that the device has been designed and tested to assure conformance to the requirements for its indications for use.